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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,711	09/11/2009	William H. Fenical	UCSD1530-5	1035

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EXAMINER	
POWERS, FIONA	

ART UNIT	PAPER NUMBER
1626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,711	FENICAL ET AL.	
	Examiner	Art Unit	
	Fiona T. Powers	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 20 December 2005 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/23/10.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending in the application.

Receipt is acknowledged of the preliminary amendments filed December 20, 2005 and June 22, 2009, which have been entered in the file.

Information Disclosure Statement

The information disclosure statement(s) (IDS) submitted on November 23, 2010 has(have) been considered. The submission(s) is(are) in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement(s) is(are) being considered by the examiner.

Drawings

The drawings filed December 20, 2005 are accepted by the examiner.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 to 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph are as follows:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of skill in the art.

See In re Wands, 8 USPQ2d 1400.

The nature of the invention is a method of treating a mammalian cell proliferative disorder such as neoplasms selected from the group consisting of mammary, small-cell lung, colorectal, leukemia, melanoma, stomach etc. and a method of treating any and all cancers.

The state of the prior art is that the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases and by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Applicants are claiming a method of treating various mammalian cell proliferative disorders and all cancers. The state of the prior art is that cancer therapy remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. It is known that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types, that cancer classification has been based on primarily on morphological appearance of the tumor and that tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy (Golub et al. page 531). Furthermore, it is known that chemotherapy is most effective against tumors with rapidly dividing cells and that cells of solid tumors divide relatively slowly and chemotherapy is often less effective against them.

The only direction or guidance present in the instant specification is data on page 31 for inhibition of colon cancer cells.

The breadth of the claims is a method of treating various mammalian cell proliferative disorders and any cancer.

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to

determine what proliferative diseases would be benefited (treated) by and would then have to determine which of the claimed compounds would provide treatment of which proliferative disease, if any.

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound of the instant claims in a method of treating the listed mammalian cell proliferative disorders and any cancer. As a result necessitating one of skill to perform an exhaustive search for which proliferative diseases can be treated by what pharmaceutical composition of the instant claims in order to practice the claimed invention.

Genetech Inc. v. Novo Nordisk A/S 42 USPQ2d 1001 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling

disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher discussed above, to practice the claimed invention herein, one of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 to 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Variables R_1, R_2 and R_3 are monovalent radicals but are defined as sulfonyl which is a divalent radical. It is not clear what else is bonded to the sulfonyl radical.

2) Claims 1, 8 and 10 do not end in a period. Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See MPEP 608.01(m).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 to 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 to 15 of U.S. Patent No. **7,176,232.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the indiscriminate selection of "some" among "many" is prima facie obvious. See In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity.

One of ordinary skill in the art would thus be motivated to make the claimed compounds which are embraced by the prior art in order to obtain additional beneficial products which would be useful for the same purpose. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instantly claimed invention would have been rendered obvious to one skilled in the art.

Claims 1-8 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. **12/638,860.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the indiscriminate selection of "some" among "many" is prima facie obvious. See In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity.

One of ordinary skill in the art would thus be motivated to make the claimed compounds which are embraced by the prior art in order to obtain additional beneficial products which would be useful for the same purpose. The instant claimed invention would have been suggested to one skilled in the art and

therefore, the instantly claimed invention would have been rendered obvious to one skilled in the art..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 10 to 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 to 3 of U.S. Patent No. **7,176,233** and claims 1-27 of U.S. Patent No. **7,635,712.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the indiscriminate selection of "some" among "many" is prima facie obvious. See In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity.

One of ordinary skill in the art would thus be motivated to make the claimed compounds which are embraced by the prior art in order to obtain additional beneficial products which would be useful for the same purpose. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instantly claimed invention would have been rendered obvious to one skilled in the art.

Claims 8 and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 to 15 of U.S. Patent No. **7,179,834.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the indiscriminate selection of "some" among "many" is prima facie obvious. See In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity.

One of ordinary skill in the art would thus be motivated to make the claimed compounds which are embraced by the prior art in order to obtain additional beneficial products which would be useful for the same purpose. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instantly claimed invention would have been rendered obvious to one skilled in the art.

Allowable Subject Matter

No claim is allowed.

The references made of record and not relied upon show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Mon - Thurs 6:15 am - 2:45 pm (in the office) and Fri 7:00 am - 5:30 pm (telework day).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fiona T. Powers/
Primary Examiner, Art Unit 1626

ftp

March 4, 2011